

**K163629 Audit MicroControls Linearity FD Tumor Markers II**Mar 10, 2017  
78 days to decisionK163629 · Product code: **JJY** · Immunology  
Source: <https://www.510kdatabase.net/k163629/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received         | Dec 22, 2016                                      |
| Decision date         | Mar 10, 2017                                      |
| Days to decision      | 78 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Aalto Scientific, Ltd.</b>           |
| Location       | Mchenry, IL, US                         |
| Contact        | Robert Burda                            |
| 510(k) history | 35 submissions · 35 cleared · 1982-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163629/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026